IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

CHRISTOPHER TYLER LOFTON, et al.	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**Civil Action No. 3:05-CV-1531-L (BH)**
	§	
MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS and **JOHNSON & JOHNSON,**	§	
	§	
Defendants.	§	

ORDER

Pursuant to the District Court's *Order of Reference*, filed May 5, 2008, this matter has been referred to this Court for hearing, if necessary, and for determination. Before the Court are the following:

(1) *Defendants' Motion to Exclude or Limit Plaintiffs' Expert Testimony with Incorporated Brief* ("Mot."), filed May 2, 2008;

(2) *Appendix to Defendants' Brief in Support of Motion to Exclude or Limit Plaintiffs' Expert Testimony* ("Mot. App."), filed May 2, 2008;

(3) *Plaintiffs Response to Defendants' Motion to Exclude or Limit Experts Testimony* ("Resp."), filed June 6, 2008;

(4) *Supplemental Appendix to Plaintiffs Response to Defendants' Motion to Exclude Experts Testimony* ("Resp. App."), filed June 6, 2008; and

(5) *Defendants' Reply in Support of Motion to Exclude or Limit Plaintiffs' Expert Testimony* ("Reply"), filed June 20, 2008.

Having reviewed the pertinent filings above and the law applicable to the issues raised, *Defendants' Motion to Exclude or Limit Plaintiffs' Expert Testimony* is **GRANTED** in part and **DENIED** in part.

I. BACKGROUND

Plaintiffs have sued to recover wrongful death and survival damages resulting from the death of Christopher M. Lofton on June 3, 2000. Plaintiffs claim that Mr. Lofton suffered from a rare adverse drug reaction known as toxic epidermal necrolysis (TEN) after taking over-the-counter Motrin, an ibuprofen[1] product manufactured by Defendant McNeil Consumer Health Care, a subsidiary wholly owned by Defendant Johnson & Johnson.

Plaintiffs identified seven expert witnesses to testify at trial. Defendants seek to exclude or limit the testimony of six: Rusty Nicar, Ph.D.; Randall Tackett, Ph.D.; Evan Schlam, M.D.; Roger Salisbury, M.D.; Robert Nelson, Ph.D.; and Jerrold Dreyer, M.D.

II. APPLICABLE STANDARD

Federal Rules of Evidence 702 and 703, as interpreted in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), govern the admissibility of testimony of expert witnesses. Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Accordingly, before allowing expert testimony to be heard, a district court must be assured that the proffered witness is qualified to testify by virtue of his "knowledge, skill, experience, training, or education." *Id.* A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.

[1] Ibuprofen is a member of a large class known as non-steroidal anti-inflammatories drugs ("NSAIDs").

Wilson v. Woods, 163 F.3d 935, 937 (5th Cir. 1999). The issue is whether a particular expert has "sufficient specialized knowledge to assist the jurors in deciding the particular issues..." *Tanner v. Westbrook*, 174 F.3d 542, 548 (5th Cir. 1999) (quoting *Kumho*, 526 U.S. at 156). The decision to admit or exclude evidence is within the discretion of the court. *See United States v. West*, 22 F.3d 586, 591 (5th Cir. 1994).

In evaluating the admissibility of expert testimony, the key factors are relevance and reliability. *Daubert*, 509 U.S. at 589 (under Rule 702, expert testimony must be "not only relevant, but reliable"). The relevancy requirement ensures that the expert testimony will actually "assist the trier of fact to understand the evidence or to determine a fact in issue." *Id*. Federal Rule of Evidence 401 defines relevant evidence as that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. "Expert testimony which does not relate to any issue on the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 590.

The reliability requirement ensures that the expert testimony is "supported by appropriate validation" and "establishes a standard of evidentiary reliability." *Id*. This determination requires the court to assess "whether the reasoning or methodology underlying the testimony is scientifically valid and...whether that reasoning or methodology properly can be applied to the facts in issue." *Id*. at 593. To assist courts in this determination, the Supreme Court has suggested that trial courts examine a nonexclusive list of factors including whether a theory or technique has or can be tested, published, subjected to peer review, whether it has or can be subjected to standards controlling its operation, the known or potential rate of error, and whether it is generally accepted. *Id*. at 593-94. The Court also instructed trial courts to "be mindful of other applicable rules," such as Rules 703,

706, and 403. *Id*. at 595. *Kumho* stressed that the *Daubert* factors may be relevant to the reliability of experience-based testimony. The overarching goal of *Daubert's* gate-keeping requirement, however, is to ensure the reliability and relevancy of expert testimony and to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. *Kumho,* 526 U.S. at 152.

The party offering the expert testimony has the burden of establishing that it is admissible under Rule 702 and the *Daubert-Kumho* standard. *See Kumho,* 526 U.S. at 147; *see also Mathis v. Exxon Corp.*, 302 F.3d 448, 459-460 (5th Cir. 2002). "Notwithstanding the dictates of *Daubert* and its progeny, 'the rejection of expert testimony is the exception rather than the rule,'" however. *Thomas v. Deloitte Consulting LP*, 2004 WL 1960097, *2 (N.D. Tex. Sept. 2, 2004) (quoting Fed. R. Evid. 702, Adv. Comm. Notes (2000)). *Daubert* does not change the fact that "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." *United States v. 14.38 Acres of Land, More or Less, Situated in Leflore County, Mississippi*, 80 F.3d 1074, 1078 (5th Cir. 1996). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

III. ANALYSIS

A. General Causation Opinions

Defendants first challenge the admissibility of all six experts' conclusion that Motrin can cause TEN on the grounds that this conclusion is not based on scientifically reliable methodology and is contrary to the most recent and best scientific study. (Mot. at 2).

1. *Havner* Criteria

a. Applicability

Defendants first urge the Court to apply *Merrill Dow Pharmaceuticals, Inc., v. Havner*, 953 S.W.2d 706 (Tex. 1997) to exclude the experts' testimony. (Mot. at 4-5). In *Havner*, the Texas Supreme Court reviewed the sufficiency of epidemiological evidence to support a jury verdict finding that ingesting a prescription drug during pregnancy caused a birth defect. The *Havner* court held that epidemiological studies that showed a "more than doubling of the risk" met the "more likely than not" burden of proof necessary to show causation in toxic tort cases. 953 S.W.2d at 717. Since the epidemiological studies presented to the jury in *Havner* did not show the drug in question more than doubled the risk of being born with the defect at issue, the Texas Supreme Court found the verdict lacked scientifically reliable evidence of causation. *Id*. at 718. Defendants contend that epidemiological studies that do not meet the *Havner* requirements do not assist Plaintiffs in meeting their burden of proof and therefore are not relevant and should be excluded under the *Daubert* standard. (Mot. at 4-5) (citing *Cano v. Everest Minerals Corp.*, 362 F.Supp.2d 814, 822-23 (W.D. Tex. 2005)).

At issue in the instant case is the admissibility of evidence, however, not the legal sufficiency of the evidence to establish causation. Although the Fifth Circuit has not considered whether *Havner* applies to admissibility under Federal Rule of Evidence 702,[2] courts within this district have found that the *Havner* standards are substantive state law requirements. *Burton v. Wyeth-Ayerst*

[2] In *Bartley v. Euclid, Inc.*, a Fifth Circuit panel applied *Havner* solely to the issue of sufficiency of the evidence to support a jury's finding of causation. 158 F.3d 261, 272-73 (5th Cir. 1998) *vacated*, 169 F.3d 215 (5th Cir. 1999). The panel explicitly declined to decide whether *Havner* applied to the admissibility of the evidence. 158 F.3d at 273, n. 9. The subsequent rehearing *en banc* in *Bartley* affirmed the jury's verdict but did not discuss the applicability of *Havner* to the issue of admissibility of evidence showing causation. 180 F.3d 175, 179 (5th Cir. 1999).

Labs. Div. of Am. Home Prods. Corp., 513 F.Supp.2d 719, 730 n.12 (N.D. Tex. 2007) (Fish, C.J.) (*Havner* standards are substantive, not procedural requirements); *Taylor v. Bristol-Myers Squibb Co.*, 2004 WL 2058796, *1 (N.D. Tex. Sept. 15, 2004) (Cummings, J.) (unpublished) (substantive requirements of *Havner* are irrelevant to determining admissibility under Rule 702).[3] Being persuaded by the previous decisions within this district, the Court finds that the *Havner* requirements are substantive and not applicable to the procedural question of the admissibility of evidence. *Burton*, 513 F.Supp.2d at 730 n.12; *Taylor*, 2004 WL 2058796, *1.

b. No Causal Link

Defendants next claim that expert testimony on causation should be excluded because none of the three seminal peer-reviewed studies can be relied on to show a causal link between ibuprofen and TEN or Stevens-Johnson Syndrome ("SJS"), the less severe form of TEN. (Mot. at 7-8). The three studies are the Roujeau study and the 2003 and 2008 Mockenhaupt studies. (*Id.*; *see* Mot. App. at 656, 143:24 - 144:18). Defendants contend that expert testimony based on the Roujeau and 2008 Mockenhaupt studies is inadmissible because these two studies do not show a doubling of the risk. (Mot. at 8). Defendants also contend that the only study showing a doubling of the risk, the 2003 Mockenhaupt study, is no longer reliable because the 2008 Mockenhaupt study superseded it. *Id.*

These objections are premised upon application of the *Havner* criteria, which the Court has found is not applicable to the issue of admissibility. Defendants have not shown that the opinions

[3]Defendants also cite to several other cases within the Fifth Circuit, but each of the cited portions of the cases considered *Havner* in the context of sufficiency of the evidence in a motion for summary judgment, not in the context of admissibility. (Mot. at 4, n.17) (citing *Cotroneo v. Shaw Env't & Infrastructure, Inc.*, 2007 WL 3145791, *4 (S.D. Tex. Oct. 25, 20070 (granting summary judgment because plaintiffs lacked evidence showing radiation exposure put them at twice the risk of developing injuries); *Burton*, 513 F.Supp.2d at 731-32 (denying summary judgment because the challenged studies introduced some evidence of causation); *Martin v. Home Depot U.S.A., Inc.*, 369 F.Supp.2d 887, 891-92 (W.D. Tex. 2005) (granting summary judgment because plaintiffs failed to submit a single scientific study supporting their theory of general causation).

based on the two Mockenhaupt studies are either not relevant or unreliable. Both the 2003 and 2008 Mockenhaupt studies are tested, published, peer-reviewed epidemiological studies on SJS and TEN. Further, the validity of expert testimony based upon the 2003 study in light of the more recent 2008 study is a question of weight, not admissibility. *See Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 354 (5th Cir. 2007) (expert need not back his opinion with published studies that unequivocally support his conclusion); *Peteet v. Dow Chemical*, 868 F.2d 1428, 1433 (5th Cir. 1989) (absence of scientific consensus does not affect admissibility of an expert's opinion). As such, testimony based on the Mockenhaupt studies should not be excluded for lack of causal link under *Havner*.

2. Epidemiological Evidence

Defendants next object to the experts' purported ignorance of the best epidemiological evidence available. (Mot. at 9-11).

a. Failure to Consider Most Recent Study

Defendants first contend that the failure to consider the 2008 Mockenhaupt study demonstrates that the opinions on causation are unreliable. As stated above, this objection goes to the weight, not the admissibility, of the evidence. *See Knight*, 482 F.3d at 354.

b. Reliance on Case Reports

Defendants next contend that the methodology Plaintiffs' experts used is flawed because the experts relied on case reports, and, according to Defendants, "case reports raise questions, they do not answer them." (Mot. at 9) (quoting *McClain v. Metabolife Int'l, Inc.* 401 F.3d 1233, 1254 (11th Cir. 2005)). Case reports, sometimes called case series, are reports in medical journals describing clinical events involving one or a few individuals. Reference Manual on Scientific Evidence 474, (Federal Judicial Center, 2d ed. 2000). They are often the first source to publish a new disease or

the association between a medication and a disease, and there are a number of instances in which later epidemiological studies have both confirmed and failed to confirm initial case reports. *Id*. Case reports lack controls and do not provide as much information as controlled epidemiological studies, but the information they contain can still be useful because they are often all that is available on a particular subject. *Id*. at 475.

The Fifth Circuit has not explicitly addressed whether case reports can be relied upon in expert opinions; it has held, however, that case reports by themselves are insufficient to establish causation. *Black v. Food Lion, Inc.*, 171 F.3d 308, 313 n.2 (5th Cir. 1999) (case reports are insufficient to establish causal relationship between trauma and fibromyalgia, but absence of evidence does not mean that causality does not exist, rather that appropriate epidemiological studies have not been performed). This is not the situation in the case at bar, since the opinions provided by the experts also relied upon published or sponsored studies and published case series. (*See e.g.* Mot. App. at 48-50, 91-94, 229-232, 365-374); *see also* Reference Manual on Scientific Evidence at 475 (causation based on case studies must be regarded with caution, but case studies may be carefully considered in light of other information available). In the Fifth Circuit, "questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration." *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 422 (5th Cir. 1987) (citing *Dixon v. Int'l Harvester Co.*, 754 F.2d 573, 580 (5th Cir. 1985).

c. Failure to Separate NSAIDs

Defendants also object that the experts did not separate classes of NSAIDs. As with case reports, this objection relates to the bases and sources of an expert's opinion and is a question best

left to the jury. *Id*.

d. No Publication and Peer Review

Defendants contend that Plaintiffs' experts "have dressed up their analysis to seem scientifically sound and based on epidemiology." (Mot. at 10). Defendants assert that save one exception, none of the methods or conclusions presented in the reports have ever been published or peer-reviewed. There is no requirement that an expert back his opinion with published studies that unequivocally support his conclusion; where an expert otherwise reliably utilizes scientific methods to reach a conclusion, a lack of textual support goes to the weight, not the admissibility, of the expert's testimony. *Knight*, 482 F.3d at 354.

3. Negation of Prior Study by Recent Study

Finally, Defendants contend that the 2008 Mockenhaupt study negates prior assumptions of causation. (Mot. at 11). They object to expert testimony that relied in part upon a 2006 Food and Drug Administration ("FDA") statement that there were risks of SJS and TEN associated with ibuprofen use because the FDA did not have the benefit of the 2008 Mockenhaupt study, which found no doubling of the risk. The fact that a more recent study provides contrary evidence to a previous finding by the FDA is something that should be addressed during cross-examination, not in a motion to exclude. *Daubert*, 509 U.S. at 596.

Defendants also assert that the FDA's assumption of a causal link between ibuprofen and SJS/TEN does not prove causation because the standard for causation used by a regulatory agency differs from that used in a court of law. In support of this second assertion, Defendants cite to *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 198 (5th Cir. 1996), and *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002). Both *Allen* and *Rider* are

distinguishable because neither case had epidemiological studies to support the plaintiff's theory of causation. Here, the experts only relied in part upon the FDA statement for their theory of causation; they also relied upon published epidemiological studies, and case reports. Questions relating the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left to the jury. *Viterbo*, 826 F.2d at 422. Thus, both of Defendants' objections regarding opinions that relied upon the FDA statement address the weight, not the admissibility, of the evidence. *See Peteet*, 868 F.2d at 1433.

In sum, Defendants' objections to expert testimony on causation all address either the weight or the sufficiency of the evidence and not its relevance or reliability. Plaintiffs' expert testimony on causation is therefore admissible for further consideration. *Daubert*, 509 U.S. at 589.

B. Defective Design Theory

Defendants next move to exclude Dr. Tackett's theory that pure S+ ibuprofen is less likely to induce SJS/TEN than the racemic mixture of R- and S+ ibuprofen found in Motrin.[4] (Mot. at 12). Specifically, Defendants contend that Dr. Tackett's defective design theory is inadmissible because it depends on an unproven hypothesis, has not been tested, and has not been published in a peer-reviewed journal. (*Id*.; Reply at 7).

Dr. Tackett opined that published studies showed ibuprofen increased production of TNF-alpha, a signaling protein responsible for apoptosis (programmed cell death) in skin cells. (Mot. App. at 96, ¶¶131, 133; 603, 214:13-215:10). Dr. Tackett further opined that a different published

[4] The ibuprofen molecule exists in two non-superimposable mirror image forms. These two stereochemical structures are identical except that one rotates to the left (S+) and the other rotates to the right (R-) around a carbon molecule with equal magnitudes of rotation. Each of these stereoisomers is called an enantiomer, and the two enantiomers have different pharmacological properties. Racemic mixtures contain equal amounts R- and S+ ibuprofen. *See* Mot. App. at 97, ¶135.

study showed elevated levels of TNF-alpha in the blister fluids of patients with SJS. (*Id*. at 132; 603, 215:11-14). A third study showed that racemic mixtures of NSAIDs (such as ibuprofen) produced a greater number of reactive metabolites (such as TNF-alpha) than did enantiomerically pure NSAIDs. (*Id*. at 98, ¶¶138-39). Based on these published studies, Dr. Tackett and others have suggested that an enantiomerically pure preparation of S+ ibuprofen would decrease the risk of SJS/TEN due to the lower levels of reactive metabolites produced from ibuprofen. (*Id*. at 98, ¶¶139-40). Although Dr. Tackett's opinion about the increased safety from enantiomerically pure S+ ibuprofen has not been tested in vivo or published, he claims that pharmacologists often integrate several studies to explain how a drug could work. (*See* Mot. App. at 603, 216:4-217:10).

Dr. Tackett's opinion need not be published to be admissible; his methods for explaining how a drug could work need only be reliable. *Knight*, 482 F.3d at 354. Where an expert otherwise reliably uses scientific methods to reach a conclusion, the lack of published studies unequivocally supporting his conclusion goes to the weight, not the admissibility, of the testimony. *Id*. Dr. Tackett's design theory therefore meets the *Daubert* requirements of relevance and reliability.[5] *Daubert*, 509 U.S. at 593-94.

C. Personal Opinions of Conduct

Defendants next raise a series of objections to the reports by Drs. Tackett, Nelson, and Salisbury on the grounds that they contain inadmissible opinions regarding Defendants' ethical obligations, motive, state of mind, asserted knowledge, and alleged conduct concerning Motrin's

[5] In their reply, Defendants raise a new argument that Dr. Tackett's proposal for enantiomerically pure S+ ibuprofen is not a reasonable and feasible alternative to the racemic mixture used in Motrin because the alternative design has not been approved for use in the United States. (Reply at 8). This issue was not raised in the initial brief and the Court declines to address it. *Perez Librado v. M.S. Carriers, Inc.*, 2004 WL 1490304, at *9-11 (N.D.Tex. June 30, 2004) (Fitzwater, J.) (declining to consider *Daubert* objections raised for the first time in a reply brief).

history and FDA labeling requirements. (Mot. at 12). The expert testimony at issue consists of statements by Drs. Tackett, Nelson, and Salisbury expressing their personal opinions on Defendants' conduct during the FDA application process. (*See e.g.*, Mot. App. at 75-83, 88-89, 94-96, 239-47, 382).

The statements are often conclusory and unsupported by evidence; they also exceed the scope of the experts' scientific, technical, and specialized knowledge. For example, Dr. Tackett testified that Defendants "withheld and concealed critical safety information from the FDA" when it filed its application for Pediaprofen and that "McNeil is negligent for failing to disclose on their prescription labeling that stomatitis has been reported to be caused by ibuprofen in clinical trials." (Mot. App. at 77-78, ¶¶56, 57). Dr. Tackett also testified that Defendants failure to provide a more specific warning regarding SJS to American consumers of Motrin when it provided one for European consumers was "an act of gross negligence that demonstrates conscious indifference to the safety of American consumers and plaintiffs." (*Id*. at 94-95, ¶125). Dr. Salisbury testified that Defendants' decision to "conceal or withhold" two cases where children developed SJS after taking children's Motrin was "disgusting" and "demonstrated a clear disregard for the safety and welfare of consumers." (*Id*. at 240, ¶51). Dr. Nelson testified that Defendants were negligent in several respects, such as failing to disclose safety information, failing to provide an adequate warning label, and failing to notify health professionals about the degree of risk of SJS/TEN. (*Id*. at 382). Under *Daubert* these statements are not reliable because there is no explanation of the reasoning or methodology underlying what appear to be personal opinions or legal conclusions based on Defendants' alleged behavior. The statements therefore are inadmissible. *See* 509 U.S. at 590. Additionally, the submission of the personal views of Drs. Tackett, Nelson, and Salisbury as expert

testimony supplants the roles of counsel in making argument at trial and the role of the jury in interpreting the evidence. *See In re Rezullin Prod. Liab. Litig.*, 309 F.Supp. 2d 531 (S.D.N.Y. 2004).

Plaintiffs respond that these experts are qualified to testify about FDA regulations, but they do not address the admissibility of their expert opinions regarding Defendants' ethical obligations, motive, state of mind, asserted knowledge, or conduct during the FDA application process. (Resp. at 22). While the experts may testify about the FDA regulatory process, *see* Part III.D.3 *infra*, their personal opinions on Defendants' application for Motrin are inadmissible because they do not meet the *Daubert* requirements for reliability. The remainder of Plaintiffs' response either makes a conclusory, wholly unsupported assertion that their experts should be allowed to testify on this issue or addresses the pending motion for summary judgment, which is not before this Court. (*See* Resp. at 23-24).

Plaintiffs have not met their burden to show that the opinions pertaining to Defendants' ethical obligations, motive, state of mind, asserted knowledge, and alleged conduct are admissible, and the Court grants Defendants' motion to exclude on this point. *See Kumho*, 526 U.S. at 147; *see also Mathis.*, 302 F.3d at 459-460.

D. Lack of Qualifications

Defendants next contend that Plaintiffs' experts are not qualified to offer testimony concerning general causation, specific causation, or FDA labeling requirements. (Mot. at 16-23).

1. General Causation

According to Defendants, Plaintiffs' experts relied solely upon literature provided by counsel to formulate their opinions on general causation. (*See* Mot. at 16-19). Defendants appear to argue

that because none of the proffered experts specializes in the narrow field of SJS/TEN causation, they are not qualified to offer an opinion on general causation.

A review of the experts' qualifications shows that although none has specialized in the field of SJS/TEN causation, all are either Ph.D. scientists in relevant fields or medical doctors who have examined or treated patients with SJS and TEN. The fact that none is an SJS/TEN "specialist" is a question of weight, not admissibility. *Peteet*, 868 F.2d at 1431. Additionally, the Court notes that the experts also relied upon their training, background, personal experiences, and other medical literature in formulating their opinion. (*See e.g.* Resp. App. at 1076-77, 1194, 1643) (averring that testimony on general causation was based on education, training, experience, and knowledge of literature). Defendants' assertion that the experts relied solely upon a review of the literature is therefore not supported by the sworn statements. Moreover, experts are *required* to review pertinent literature before giving their opinions. Reference Manual on Scientific Evidence at 415 ("The basis of the toxicologist's expert opinion in a specific case is a thorough review of the research literature and treatises concerning effects of exposure to the chemical at issue"); *id*. at 452, 473-74 (physicians who testify on general causation are required to review pertinent literature).

Defendants fail to cite any case law to support their contention that only experts on a specific disease can testify about causation. Instead, the only cases cited in this subsection address the argument that a review of literature does not qualify one to testify as an expert. (Mot. at 16, n. 104) (citing *Newton v. Roche Labs., Inc.*, 243 F.Supp.2d 672 (W.D. Tex. 2002), and *In re Welding Fume Prods. Liab. Litig.*, 2006 WL 4507859 (N.D. Ohio Aug. 8, 2006)). In *Newton*, the magistrate judge excluded the testimony on general causation of a proffered expert who claimed to be a doctor and a pharmacologist but never earned an M.D., a Ph.D., or any degree in pharmacology. 243 F.Supp.2d

at 677. The magistrate determined that the expert in question relied solely upon an incomplete review of literature and was totally unqualified to offer an expert opinion. *Id*. at 678. *Newton* is easily distinguishable from the instant case because Plaintiffs' experts hold advanced degrees in relevant fields and have decades of appropriate experience in toxicology, epidemiology, and medicine. (*See e.g.* Resp. App. at 1098-1103 (Nicar), 1176-79 (Schlam), 1259-95 (Tackett), 1635-38 (Dreyer), 1703-24 (Nelson), 1780-1807 (Salisbury)). As for *Welding Fume*, the portion quoted by Defendants is taken out of context and does not support the proposition that experts may not review literature before testifying. In fact, *Welding Fume* explicitly found that a literature review was appropriate and helpful to a toxicologist in formulating an expert opinion. 2006 WL 4507859, at *12-13. Since the district court in *Welding Fume* permitted the challenged expert to testify, the case actually *supports* the admission of Plaintiffs' expert testimony.

For these reasons, Defendants have not shown that a review of literature provided by counsel disqualifies experts from providing testimony on general causation. The fact that Plaintiffs' counsel supplied much of the literature the experts reviewed is a question of weight, not admissibility, that can be explored on cross-examination should the case proceed to trial. *Daubert*, 509 U.S. at 596; *Viterbo*, 826 F.2d at 422.

2. Specific Causation

Defendants next object to the testimony on specific causation by Drs. Nicar, Tackett, and Nelson on the grounds that they are not medical doctors. (Mot. at 19-20).

Experts need not be medical doctors for their testimony on specific causation to be admissible. *Curtis v. M&S Petroleum, Inc.*, 174 F.3d 661, 671-72 (5th Cir. 1999) (allowing toxicologist to testify on specific causation); *Whitfield v. Tronox Worldwide, LLC*, 2007 WL

2127298, *4 (N.D. Miss. 2007) (admitting testimony of epidemiologist); *Avance v. Kerr-McGee Chem.*, LLC, 2006 WL 3912472, at *9 (E.D.Tex. Dec. 4, 2006) (admitting testimony of toxicologist); Reference Manual on Scientific Evidence at 422-27 (permitting testimony on specific causation by toxicologists); *id*. at 381-82 (sufficiently rigorous epidemiological studies used to show specific causation should be admissible even though specific causation is beyond the domain of the science of epidemiology).

Defendants recognize that cases in the Fifth Circuit have allowed toxicologists to testify on specific causation. (Mot. at 20, n. 131) (citing *Curtis*, 174 F.3d 661 and *Avance*, 2006 WL 3912472, at *9). Defendants urge the Court to adopt the "better view" as expressed in three out-of-circuit cases in which the courts excluded testimony on specific causation from toxicologists, however. *Id*. (citing *Kerner v. Terminix Int'l Co.*, 2008 WL 341363, at *4 (S.D. Ohio Feb. 6, 2008); *Conde v. Velsicol Chem. Corp.*, 804 F.Supp. 972, 1023-24 (S.D. Ohio 1992); *In re Silicone Gel Breast Implant Prod. Litig.*, 318 F.Supp.2d 879, 906-07 (C.D. Cal. 2004)). Since qualified toxicologists and epidemiologists have offered testimony on specific causation in this circuit, the Court declines to adopt the alternative view expressed in the cases cited by Defendants.

3. Labeling[6]

Defendants also object to the qualifications of Drs. Tackett, Salisbury, and Nelson regarding their testimony on the adequacy of Motrin's label in warning for signs and symptoms of TEN.[7]

[6] Plaintiffs state that their experts "are *un*qualified to offer opinions on general causation, and labeling." (Resp. at 2). Given that the relevant section on labeling argues that their experts are in fact qualified, the Court presumes that this was but one of many typographical errors in their brief.

[7] Defendants also object that the expert opinions on labeling are irrelevant because there is a statutory presumption that FDA-approved warnings and instructions are adequate. (Mot. at 14, 20) (citing Tex. Civ. Prac. & Rem. § 82.007). This objection does not address the admissibility of testimony on labeling and will not be addressed by this Court.

(Mot. at 20-23). They contend that none of the proffered experts have sufficient experience in drafting warning labels for over-the-counter ("OTC") medications.

Both Drs. Tackett and Nelson have extensive experience with FDA labeling requirements. Dr. Tackett is a pharmacologist and toxicologist who has been involved with FDA regulations as an academician for more than 20 years. (Mot. App. at 3-4). He instructed FDA and private sector employees in workshops that included presentations of applicable FDA regulations. (*Id*. at 4). Dr. Nelson worked at the FDA for approximately 20 years; his duties included new drug review, epidemiology, and post-marketing surveillance. (Mot. App. at 350, 389-90). For the past ten years, he has worked as an independent consultant on drug safety and regulatory affairs. *Id*.

Defendants contend that whatever experience Drs. Tackett and Nelson may have in drug labeling is not relevant because their experience is with prescription, and not OTC, medications. (Mot. at 21, 23). The depth of Drs. Tackett and Nelson's experience with OTC medications is not clear from the expert reports, but the Court is not persuaded that this distinction warrants exclusion of their testimony. Any doubts about the relevance of their experience as it pertains to OTC labeling is a question of weight, not admissibility. *Peteet*, 868 F.2d at 1431-32 (fact that certified expert is not a specialist in any relevant field goes to weight, not admissibility); *Viterbo*, 826 F.2d at 422.

Dr. Salisbury, unlike Drs. Tackett and Nelson, has never worked for the FDA, nor has he published any articles regarding the labeling of any drug. (*See* Mot. App. at 225-28, 251-80). He has, however, treated more than 400 SJS/TEN patients in his 36-year career as a burn surgeon and possesses a clinical perspective on how regulated drugs communicate, or fail to communicate, their risks to patients. (*Id*. at 225-26). In addition, he serves as a professor of medicine and instructs his students how to review labels for prescription and OTC medications so that they can appropriately

communicate warnings to their patients. (*Id*. at 226). Given the nature of his personal experience, Dr. Salisbury's opinion on the adequacy of Motrin's label is both relevant and reliable. *Kumho*, 526 U.S. at 152. Any lack of formal training or work experience in drafting warning labels is a question of weight, not admissibility.[8] *Peteet*, 868 F.2d at 1431-32.

E. Inadequate Expert Disclosures

Defendants next request the Court to limit the testimony of Drs. Nelson, Tackett, and Salisbury because their reports allegedly do not contain a complete statement of all opinions and the basis and reasons for them. (Mot. at 23-24).

The district court's scheduling orders required the parties to comply with Federal Rule of Civil Procedure 26(a)(2) with regards to expert testimony; no modifications or additional requirements were imposed. (*See* docket #14, 36). Rule 26(a)(2)(B) requires expert reports to contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B).[9] Rule 26(a)(2) is designed to impose a "duty to disclose

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[8] Defendants also contend that Dr. Salisbury does not possess any independent, non-litigation experience with drug labeling. (Mot. at 22). Given his extensive practical experience with SJS/TEN patients and the efficacy of warning labels in the clinical setting, this objection is without merit. Defendants' contention that Dr. Salisbury's experience as a plastic surgeon specializing in burns is likewise without merit since most SJS/TEN patients are treated in burn units. (Mot. App. at 226).

[9] Rule 26(a)(2)(B) states:

> Unless otherwise stipulated or ordered by the court, this disclosure must be accompanied by a written report - prepared and signed by the witness- if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony. The report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the data or other information considered by the witness in forming them; (iii) any exhibits that will be used to summarize or support them; (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years; (v) a list of all other cases in which, during the previous four years, the witness testified as an expert at trial or by deposition; and (vi) a statement of the compensation to be paid for the study and testimony in the case.

The Federal Rules of Civil Procedure were amended on December 1, 2007. The Court notes that Defendants cite to the previous version of the rule.

information regarding expert testimony sufficiently in advance of trial that opposing parties have a reasonable opportunity to prepare for effective cross examination and perhaps arrange for expert testimony from other witnesses. Rule 26(a)(2) Adv. Comm. Notes (1993). Expert reports should be "detailed and complete" so as "to avoid the disclosure of 'sketchy and vague' expert information." *Sierra Club v. Cedar Point Oil Co. Inc.*, 73 F.3d 546, 571 (5th Cir.1996).

Defendants contend that Drs. Nelson, Tackett, and Salisbury violated Rule 26(a)(2)(B) because the "reams of material" the experts brought with them to the depositions were not directly identified in their reports or because some opinions were based upon materials used in another lawsuit that were unavailable to Defendants in this litigation. (Mot. at 24). Plaintiffs do not dispute that the reports did not cite all of the material upon which the experts relied. (*See* Resp. at 24). Rather, they respond that all of the documents were either produced in a previous case (*Langstaff*), produced in other Motrin cases, or later produced in this case. *Id.* Plaintiffs further respond that all materials were available and that Defendants had the opportunity to copy them as desired. (Resp. at 24-25). The reasons supplied by Plaintiffs do not change the fact that their expert reports failed to contain a complete statement of all opinions and the basis and reasons for the opinions as required by the Federal Rules of Civil Procedure and the district court's scheduling order. Fed. R. Civ. P. 26(a)(2)(B).

If a party fails to provide information or identify a witness as required by Rule 26(a), "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Plaintiffs failed to provide a substantial justification for the omissions in their response, so the Court looks to see whether the violation was harmless. In evaluating whether a violation of Rule 26 is

harmless, the Court examines four factors: (1) the importance of the evidence; (2) the prejudice to the opposing party of including the evidence; (3) the possibility of curing such prejudice by granting a continuance; and (4) the explanation for the party's failure to disclose. *Texas A & M Research Fund v. Magna Transp., Inc.*, 338 F.3d 394, 402 (5th Cir. 2003). The evidence contained in the reports of Drs. Tackett, Nelson, and Salisbury is clearly important to Plaintiffs' case; without it, they will have no evidence of general causation or labeling requirements. As for the second factor, Defendants have not explained how the omission of some references prejudiced them; the chief objection is that they "simply are not required to search through numerous linear feet of documents to reconstruct the information forming Plaintiffs' experts' opinions." (Mot. at 24). The third factor suggests that any potential prejudice could be cured through a request for a continuance to conduct a second deposition; Defendants, however, did not ask for such a continuance in their prayer for relief.[10] As for the fourth factor, Plaintiffs did not offer a suitable explanation for the omissions; they only state that the expert reports are extensive and that the documents were available for examination. (Resp. at 24). Thus, the first and third factors weigh in favor of Plaintiffs; the second factor slightly favors Defendants; and the fourth factor favors Defendants. Considering these factors together, the Court finds that the violation of Rule 26(a)(2)(B) was harmless and declines to limit the expert testimony as requested by Defendants. *Texas A & M Research Fund*, 338 F.3d at 402; Fed. R. Civ. P. 37(c)(1).

F. <u>Cumulative Testimony</u>

Finally, Defendants contend that Plaintiffs'expert testimony is cumulative and request the

[10] The Court notes that the parties filed a joint motion to abate proceedings pending the Supreme Court's resolution of *Wyeth v. Levine*, 128 S.Ct. 1118 (Mem.). (Docket #87). If the District Court grants the motion to abate, the need for a continuance would be moot since Defendants would have additional time to conduct a second deposition if they file a motion to do so and if that motion is granted.

Court to limit the number of testifying experts. (Mot. at 25; *see* Reply at 6). The cumulative nature of the expert testimony is a determination better made at trial after the parties have actually called the experts to testify.

IV. CONCLUSION

For the reasons stated above, *Defendants' Motion to Exclude or Limit Plaintiffs' Expert Testimony* is **GRANTED** in part and **DENIED** in part. The motion is **GRANTED** as to the opinions of Drs. Tackett, Nelson, and Salisbury as they pertain to Defendants' ethical obligations, motive, state of mind, asserted knowledge, and alleged conduct concerning Motrin's history and FDA labeling requirements. The motion is **DENIED** in all other respects.

SO ORDERED on this 25th day of July, 2008.

IRMA CARRILLO RAMIREZ
UNITED STATES MAGISTRATE JUDGE